

REMARKS / ARGUMENTS

Status of Claims

Claims 1-10, 13-16, 18, 20-26, 29-35, 37 and 39 are pending in the application and stand rejected. Applicants have amended Claims 1, 8, 10, 14, 16, 18, 20, 25, 33, 37, and 39, canceled Claims 7, 13, 21-24, and 35, and added new Claims 40-43, leaving Claims 1-6, 8-10, 14-16, 18, 20, 25-26, 29-34, 37, and 39-43 for consideration upon entry of the present Amendment.

Applicants respectfully submit that the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) have been traversed, that no new matter has been entered, and that the application is in condition for allowance.

Rejections Under 35 U.S.C. §102(b)

Claim 21 stands rejected under 35 U.S.C. §102(b) as being anticipated by Scanlon (U.S. Patent No. 5,853,005, hereinafter "Scanlon").

Applicants traverse this rejection for the following reasons.

Applicants have canceled Claim 21 without prejudice or disclaimer.

Rejections Under 35 U.S.C. §103(a)

Claims 1, 7-10, 13-15, 18, 20 and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schlager et al. (U.S. Patent No. 6,024,705, hereinafter "Schlager").

Claims 16, 24-26, 31, 34, 35 and 37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Scanlon.

Claims 2-6, 22, 23, 29, 30, 32 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Schlager et al. in view of Scanlon.

Applicants traverse these rejections for the following reasons.

Applicants respectfully submit that the obviousness rejection based on the References is improper as the References fail to teach or suggest each and every element

of the instant invention in such a manner as to perform as the claimed invention performs. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). The Examiner must meet the burden of establishing that all elements of the invention are taught or suggested in the prior art. MPEP §2143.03.

Additionally, Applicants respectfully submit that “To establish inherency, the extrinsic evidence ‘must make clear that the missing *descriptive matter is necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances *is not sufficient.*” (emphasis added) MPEP §2112 citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” MPEP §2112 citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat App. & Inter. 1990) (emphasis in original).

Dependent claims inherit all of the limitations of the respective parent claim and any intervening claim.

Regarding Independent Claims 1 and 18

Applicants have amended Claims 1 and 18 to now recite, inter alia “...*determining timing of a gating signal prior to displacement of a body part of a patient based upon the acquired information...*”. No new matter has been added as antecedent support may be found in the application as originally filed, such as originally filed Claim 7, for example.

To allege obviousness of Claim 7, which has been incorporated into Claims 1 and 18, the Examiner asserts that teaching by Schlager of linear prediction coefficients *permits* the SCG analysis instrument to provide information regarding the determination

of a timing interval between atrial depolarization and ventricular stimulation pulse events prior to displacement of a body part of a patient. [Present Paper, Page 6].

Applicants respectfully disagree. Schlager teaches "...LPA coefficients are used ... to *determine a classification* of the patent's [sic] waveforms as either normal or ischemic." (emphasis added) and "...Classification of SCG waveforms as represented by the LPA coefficients for myocardial ischemia...represented in the SCG waveform" [4:30-33; 52-55]. Schlager additionally teaches "linear prediction coefficient determination function 11 in which the LPA coefficients are *calculated for time segments of the SCG wave...* and *segments ... are discarded*. This establishes SCG waveforms as a series of numerical LPA coefficients for *processing of the total waveform for classification or for estimation purposes* ...The output includes a *probability figure indicating the strength of the certainty of the diagnosis...*" (emphasis added) [6:2-21]

In view of the foregoing, Applicants submit that Schlager teaches a mathematical manipulation to select segments of a collected waveform that are anticipated to provide increased accuracy of a diagnostic determination of *the total waveform* (which must therefore occur *following* data acquisition of the *total waveform*) and to *predict an accuracy of the diagnostic determination*, which Applicants submits is *substantially different* from the claimed *determining timing of a gating signal prior to displacement of a body part of a patient*. Therefore, Applicants submit that the *accuracy prediction (following data acquisition)* of Schlager fails to teach or suggest the claimed *determining timing of a gating signal prior to displacement of a body part of a patient*.

Furthermore, Applicants respectfully submit that it appears the allegation that LPA coefficients *permit* the SCG analysis instrument to provide pulse events prior to displacement of a body part implies an inherency analysis to the teachings of Schlager, as the Examiner has not established where such a limitation is specifically taught or suggested by Schlager. Applicants submit that use of the LPA coefficients to *determine a classification* of the patient's waveforms as either normal or ischemic following collection thereof does not *necessarily* require determining timing of a gating signal *prior to* displacement of a body part of a patient as presently claimed in Claim 1, as evidenced

by the very language of Schlager itself (see discussion above regarding the Schlager diagnostic determination of *the total waveform*, which must therefore occur following data acquisition of the *total* waveform).

Accordingly, Applicants submit that Schlager fails to teach or suggest each and every element of the claimed invention arranged to perform as the claimed invention performs, and that absent such teaching Schlager cannot support a prima facie case of obviousness.

Regarding Independent Claim 10

Applicants have amended Claim 10 to now recite, inter alia “...*calculating a first derivative of the acceleration waveform to obtain a jerk waveform; determining a salient-peak of the jerk waveform; and gating using the salient-peak as a trigger point....*”. No new matter has been added as antecedent support may be found in the application as originally filed, such as originally filed Claim 13, for example.

To allege obviousness of Claim 13, which has been incorporated into Claim 10, the Examiner acknowledges that Schlager fails to teach or suggest use of the jerk waveform or salient peak, and notes that the computer processing is *capable of* performing the function as claimed and would be obvious to one with ordinary skill in the art at the time the invention was made to perform calculations to provide a trigger for cardiac gating. (Present Paper, Page 7). Applicants respectfully disagree.

Schlager teaches “Linear prediction analysis is a well known form of mathematical modeling used to *represent a waveform* by a relatively small number of model coefficients...[yielding] a mathematical model that will contain substantially all, if not all, of the information resident in the original waveform...to determine the ak coefficients so as to *minimize the mean square error, E... the partial derivative of E* with respect to each coefficient...should be zero” (emphasis and clarification added)[12:37-13:10].

Here, Applicants find Schlager to teach a mathematical modeling to *represent a waveform*, and *calculations* including a partial derivative *to reduce an error of the*

model that represents the waveform.

Applicants respectfully submit that such representation and calculations as taught by Schlager are *substantially different* from and wholly absent any teaching or suggestion to arrive at the claimed *calculating a first derivative of the acceleration waveform to obtain a jerk waveform; determining a salient-peak of the jerk waveform; and gating using the salient-peak as a trigger point.*

Furthermore, Applicants respectfully submit that it appears the allegation that the mathematical modeling and computer processing *is capable or performing* the function as claimed implies application of an inherency analysis to the teachings of Schlager. Applicants submit that use of the mathematical modeling to represent a waveform and reduce an error of a model does not *necessarily* require *calculating a first derivative* of the acceleration waveform and *determining a salient-peak* of the jerk waveform as presently recited in Claim 10.

Accordingly, Applicants submit that Schlager fails to teach or suggest each and every element of the claimed invention arranged to perform as the claimed invention performs, and that absent such teaching Schlager cannot support a prima facie case of obviousness.

Regarding Independent Claims 16, 25, and 37

The Examiner acknowledges that Scanlon fails to teach each and every element of the claims with respect to gating, and alleges that it would have been obvious to one with ordinary skill in the art to utilize the non-electrical sensor to acquire information for gating.

Applicants have amended Claims 16, 25, and 37 to include elements from Claim 7 to now recite, inter alia, "...determining timing of a gating signal prior to displacement of a body part of a patient based upon the acquired information...". No new matter has been added as antecedent support may be found in the application as originally filed, such as originally filed Claim 7, for example.

Applicants respectfully submit that Scanlon fails to teach or suggest the elements incorporated from Claim 7 into Claims 16, 25, and 27, and therefore cannot support a prima facie case of obviousness.

Regarding Claim 33

To allege obviousness of Claim 33, the Examiner acknowledges that Schlager fails to disclose a process for respiratory gating, and looks to disclosure of a pressure transducer by Scanlon to cure the deficiency. [present paper, page 11]. Further, the Examiner acknowledges that Schlager does not specifically disclose a 'salient peak' and remarks that subsequent computer processing is described by Schlager [10:25-55] *that would allow capability* of analyzing the filtered signal for salient peaks and providing a trigger point for gating. [present paper, page 11]

Schlager teaches "...An envelope function...is formed by connecting a sequence of local maximal points...the autocorrelation function is then computed from the positive envelope waveform...Any offset bias or slope is then removed along with a smoothing of the autocorrelation function..." [10:25-55]

Applicants submit that Schlager teaches connecting a sequence of local maximal points to create an autocorrelation function and smoothing of the autocorrelation function and is absent any teaching or suggestion of the "...*integrating the acceleration signal twice to obtain a resultant signal; band pass filtering the resultant signal to remove frequencies that cause drift in the resultant signal and frequencies corresponding to cardiac motion to obtain a filtered signal; analyzing the filtered signal for salient peaks...*" recited in Claim 33. Applicants further submit that the teaching of a pressure transducer by Scanlon fails to cure this deficiency.

Furthermore, Applicants respectfully submit that it appears the allegation of subsequent computer processing *that would allow capability* of analyzing the filtered signal for salient peaks implies application of an inherency analysis to the teachings of Schlager.

Applicants submit that the creation and smoothing of the autocorrelation function taught by Schlager *does not necessarily* require *integrating the acceleration signal twice*

to obtain a resultant signal; band pass filtering the resultant signal to remove frequencies that cause drift in the resultant signal and frequencies corresponding to cardiac motion to obtain a filtered signal; analyzing the filtered signal for salient peaks as presently recited in Claim 33.

Accordingly, Applicants respectfully submit that the combination of Schlager and Scanlon fails to teach or suggest each and every element of the claimed invention arranged to perform as the claimed invention performs, and therefore cannot support a prima facie case of obviousness.

In view of the foregoing, Applicants submit that the References fail to teach or suggest each and every element of the claimed invention and are therefore wholly inadequate in their teaching of the claimed invention as a whole and therefore cannot properly be used to establish a prima facie case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a), which Applicants consider to be traversed.

Regarding New Claims 40 - 43

Applicants have added new Claims 40 through 43, which depend respectively from Claims 16, 18, 25, and 37, to now claim originally disclosed but previously unclaimed subject matter. No new matter has been added as antecedent support may be found in the application as originally filed, such as originally filed Claim 13, for example.

In view of the amendment and remarks set forth above regarding the allowability of Claims 16, 18, 25, and 37, Applicants submit that new Claims 40 - 43 are directed to allowable subject matter and respectfully requests entry and notice of allowance thereof.

In light of the forgoing, Applicants respectfully submit that the Examiner's rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) have been traversed, and respectfully requests that the Examiner reconsider and withdraw these rejections.

If a communication with Applicants' Attorneys would assist in advancing this case to allowance, the Examiner is cordially invited to contact the undersigned so that any such issues may be promptly resolved.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 07-0845. In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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